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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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27667 7590 06/03/2008  
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EXAMINER

BRUSCA, JOHN S

ART UNIT

PAPER NUMBER

1631

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DELIVERY MODE

06/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/600,935	<b>Applicant(s)</b> MANSURIPUR ET AL.	
	<b>Examiner</b> John S. Brusca	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 5, 28, 40-63 and 72-80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-27, 29-39 and 64-71 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. This application has been transferred to a new examiner.
2. The amendment to the specification filed 17 August 2007 has been entered. The amendment to the claims filed 31 March 2008 has been entered. This Office action refers to the numbering of the claims as in the most recent entered claim set of 31 March 2008.

#### ***Status of the Claims***

3. Claims 1-80 are pending.  
Claims 5, 28, 40-63, and 72-80 are withdrawn  
Claims 1-4, 6=27, 29-39, and 64-71 are rejected.

#### ***Election/Restrictions***

4. Upon further consideration the species of storage device structures 1) parking lot comprising channels and gates in the form of a racetrack as in claim 9 and 29, and 2) microfluidic devices as in claims 30-39 originally elected in the election filed 22 November 2006 are rejoined as the two embodiments are not mutually exclusive. Therefore the species of storage devices comprising channels and gates in the form of a race track as in claims 9 and 29 are **rejoined**.
5. The Office action mailed 17 April 2007 failed to include claim 9 in the nonelected species of storage device structures comprising channels and gates in the form of a racetrack; as noted above that species is rejoined and claim 9 is examined. the Office action mailed 17 April 2007 failed to note that claims 72-80 are drawn to nonelected Group 3 and are therefore withdrawn.

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Claims 40-63 and 72-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 22 November 2006. The restriction was made final in the Office action mailed 17 April 2007.

Claims 5 and 28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 22 November 2006.

6. In any future claim sets the applicants should state the claim status of withdrawn claims as noted in this Office action.

***Priority***

7. The claim to benefit of provisional application No. 60/391639 is perfected in view of the amendment to the specification filed 17 August 2007.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-4, 6-27, 29, 33, 35-37, 39, and 64-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must transport individual molecules of DNA to desired locations, add desired nucleotide sequences or other spatially define markers to the molecule, and determine the sequence of an individual DNA molecule as part of a process of storing and reading data. For the reasons discussed below, there would be an unpredictable amount of experimentation required to make and use the claimed invention.

b) The specification presents to utilize microfluidic devices and electrophoretic devices to move DNA molecules without providing guidance to be able to determine where an individual molecule is with the precision required to execute memory write and read operations on an individual molecule. The specification does not provide specific guidance regarding how data is to be processed for encoding into the sequences of DNA molecules, nor does the specification provide guidance regarding how DNA sequences of individual molecules are to be processed to regenerate stored data. The specification provides guidance to synthesize individual molecules to comprise a desired sequence on pages 19-33. Write mechanism 1 requires in situ chemical synthesis. In situ synthesis is a time consuming and complicated procedure and the specification

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does not show how such a procedure is compatible with a read-write memory storage apparatus that functions with a practical time period. Write mechanism 2 individual nucleotides are added to a chamber containing the growing chain and a polymerase, but the specification does not address how to prevent errors due to inlet of more than one nucleotide, or how a polymerase incorporates a single substrate molecule with perfect efficiency even though enzymes generally require minimum concentrations of substrates to function. Write mechanisms 3-5 require modification of individual DNA molecules or other polymers at precise positions, but the specification does not provide specific guidance for locating modifications at precise positions in an individual molecule. Read mechanisms 1 and 2 require use of a nanopore or atomic force microscopy without providing specific guidance as to the nanopore or the parameters that can be measured to sequence through a nanopore or atomic force device. the specification provides guidance to use optical tweezers to move individual molecules from one part of the apparatus to another.

c) The specification does not provide working examples of any embodiment of the claimed invention.

d) The nature of the invention, synthesis of sequences or markings on individual molecules and subsequent determination of sequence or other features on individual molecules, is complex.

e) Rhee et al., published 4 years after the effective filing date of the instant application, shows that nanopore sequencing is a promising idea that has not yet been reduced to practice. Among the practical problems to nanopore sequencing that Rhee et al. notes are that alpha-hemolysin pores and other nanopores used allow for discrimination of some sized of single

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stranded DNA, but do not allow for sequencing. McCauley et al. review the use of optical tweezers to manipulate DNA. McCauley et al. show in figure 1 that optical tweezers have been used to stretch DNA molecules to which beads have been attached to measure physical parameters of DNA molecules. McCauley et al. further details experiments using DNA bound to protein molecules that are manipulated by optical tweezers. McCauley et al. does not show use of optical tweezers to transport DNA within a device.

f) The skill of those in the art of molecular biology is high.

g) Because the claimed subject matter is drawn to aspects of manipulation of individual molecules that are not shown in the prior art, the predictability of the claimed subject matter is poor.

h) The claims are broad in that they encompass subject matter not detailed sufficiently in the specification or the prior art to avoid undue experimentation.

The skilled practitioner would first turn to the specification for guidance in practicing the claimed subject matter, however the specification does not provide working examples or sufficiently detailed guidance to manipulate individual molecules as required by the claimed subject matter. As such, the skilled practitioner would turn to the prior art for the guidance that is missing from the specification. However the prior art does not show methods of manipulation of individual molecules as in the claimed subject matter. Finally said practitioner would turn to trial and error experimentation to practice the claimed subject matter. Such represents undue experimentation.

10. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention in the Office action mailed 17 April 2007 is withdrawn in view of the amendment to claim 8 filed 31 March 2008.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23 and 24 are indefinite for recitation of the phrases “pull the strands around” and “pull it around” because the destination of the strands is not clear.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 30-32, 34, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Lagally et al.

The claims are drawn to a microfluidic device that moves DNA molecules to different locations within the device. In some embodiments the device comprises pumps and valves. In some embodiments the device comprises an electrophoresis device.

Lagally et al. shows in figure 1 a microfluidic device that comprises valves, pumps, and a capillary electrophoresis device. The device is used to amplify DNA by in situ PCR, followed by analysis of the DNA products by capillary electrophoresis within the device. Representative



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results of the analysis of the DNA produced in the reactions is shown in figure 2. Lagally et al. provides on pages 567-568 details of how the microfluidic device operates, including discussion of moving the DNA samples by pumping and use of valves.

***Claim Rejections - 35 USC § 103***

14. The following rejections are withdrawn in view of the arguments presented on pages 22-25 in the response filed 17 August 2007.

15. The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. [Scientific American, volume 253, 1985, pages 48-56] in view of Rothmund [US Patent 5,843,661] in view of Lackritz et al. [US Publication 2002/0056639] is withdrawn.

16. The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. in view of Rothmund in view of Lackritz et al., in further view of Meller et al. [Physical Review Letters, April 2001, volume 86, pages 3435-3438] is withdrawn.

17. The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. in view of Rothmund in view of Lackritz et al., in further view of Wang et al. [US PG PUB 2002/0181837] is withdrawn.

18. The rejection of claims under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. in view of Rothmund in view of Lackritz et al., in further view of Lee et al. [US Patent 6,905,586] is withdrawn.

***Conclusion***

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/  
Primary Examiner  
Art Unit 1631

jsb